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PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,844

Applicant(s)

ISAAC ET AL.

ExaminerKristen Mullen (formerly
Droesch)**Art Unit**

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-23 and 25-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/8/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Recharge circuitry shown in Fig. 3.

Recharge circuitry shown in Fig. 4.

2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 14, and 28 are generic.

3. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the

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prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Derrick Reed on 9/14/04 a provisional election was made with traverse to prosecute the invention of Fig 4, claims 1-8,10-23, 25-36. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9, and 24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claim 23 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). It is unclear whether the language "either claims 15-22" is alternative language. The examiner suggests using language such as --any one of claims 15-22--. See MPEP § 608.01(n) for further examples of acceptable multiple dependent claim language

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 32 recites the limitation "the capacitor charge cycle" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-2, 10-15, 25-27, are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (5,674,248).

Regarding claims 1-2, Kroll et al. shows a sensing circuit configured to sense physiological cardiac events, a pulse generator configured to deliver electrical stimulation energy to selected cardiac tissue upon the sensing of selected cardiac events, the pulse generator having storage capacitors (30) that store the stimulation energy, a Lithium

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Pentoxide (LP) or Lithium Silver Vanadium Oxide (LSVO) battery (50, 70) coupled to the storage capacitors, the LP or LSVO battery providing a charging current to charge the storage capacitors to preselected energy level; and a recharging circuit (45, 48, 63, 67) coupled to the LP or LSVO battery and configured to deliver recharging current to the LP or LSVO battery (Figs. 2-3; Col. 2, line 14-Col. 5, line 69).

With respect to claims 14-15, Kroll et al. shows a method of recharging the LP or LSVO battery comprising the step of recharging the LP or LSVO battery to a preselected voltage level (Figs. 2-3; Col. 2, line 14-Col. 5, line 69).

With respect to claim 10, Kroll et al. shows a supply battery (45, 63), wherein the recharging circuit (48, 67) is coupled between the supply battery (45, 63) and the LP or LSVO battery (50, 70) (Figs. 2-3; Col. 2, line 14-Col. 5, line 69).

Regarding claims 11-13, and 25-27, Kroll et al. shows the LP or LSVO battery (50, 70) has a stored energy density and the supply battery (45, 63) has a stored energy density greater than that of the LP battery; the step of controlling recharging of the SVO battery by the supply battery; the supply battery (45,63) comprises a relatively high energy density battery and comprises Lithium Carbon Monofluoride (CFx) (Figs. 2-3; Col. 2, line 14-Col. 5, line 69).

12. Claims 1-2, 4, 6-8, 14-15, 17-18, 20, and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Munshi et al. (5,411,537).

Regarding claims 1-2, Munshi et al. shows a sensing circuit configured to sense physiological cardiac events, a pulse generator (62) configured to deliver electrical stimulation energy to selected cardiac tissue upon the sensing of selected cardiac events, the pulse generator having storage capacitors that store the stimulation energy, a Lithium

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Pentoxide (LP) or Lithium Silver Vanadium Oxide (LSVO) battery (92) coupled to the storage capacitors, the LP or LSVO battery providing a charging current to charge the storage capacitors to preselected energy level; and a recharging circuit (88, 90) coupled to the LP or LSVO battery and configured to deliver recharging current to the LP or LSVO battery (Figs. 1-3; Col. 7, lines 4-26).

With respect to claim 4, Munshi shows a LP or LSVO battery voltage detector (90) (Fig.3; Col. 11, line 42-Col. 12, line 30).

Regarding claim 6, Munshi et al. shows LP or LSVO battery has a maximum energy capacity (Col. 11, lines 1-21).

With respect to claim 7, Munshi et al. shows the LP or LSVO battery is periodically recharged independent of the number of occurrences of the delivery of stimulation energy (Col. 11, line 42-Col. 12, line 30).

Regarding claim 8, Munshi et al. shows the recharging circuit includes circuitry to determine the maximum voltage across the LP battery (Col. 11, line 42-Col. 12, line 30).

With respect to claims 14-15, Munshi et al. shows a method of recharging the LP or LSVO battery comprising the step of recharging the LP or LSVO battery to a preselected voltage level (V_N) (Figs. 1-3; Col. 11, line 42- Col. 12, line 30)

Regarding claims 17-18, Munshi et al. shows the implantable device includes a battery voltage monitor (88, 90), and the method steps of monitoring the voltage across the SVO battery and recharging the SVO battery when the monitored voltage drops below a preselected value (V_{min}); and terminating recharging the SVO battery when the monitored battery voltage exceeds a preselected value (V_N) (Col. 11, line 42-Col. 12, line 30).

With respect to claim 20, Munshi shows the SVO battery has a maximum energy storage capacity, and the method the step of recharging the SVO battery when a preselected portion of the maximum stored energy has been depleted (Col. 8, lines 30-33, lines 63-66; Col. 11, line 42-Col. 12, line 30).

With respect to claims 22-23, Munshi et al. further shows recharging the SVO battery utilizing a recharging current no greater than a preselected value to prevent degradation of performance characteristics of the battery, and terminating recharging of the SVO battery (Col. 11, lines 1-21; Col. 11, line 42-Col. 12, line 30).

13. Claims 1-3, 10-16, 22-23, 25-28, 30-31, 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by anticipated by Kroll (6,546,807).

Regarding claims 1-2, Kroll shows a sensing circuit configured to sense physiological cardiac events, a pulse generator configured to deliver electrical stimulation energy to selected cardiac tissue upon the sensing of selected cardiac events, the pulse generator having storage capacitors (150, 152) that store the stimulation energy, a Lithium Pentoxide (LP) or Lithium Silver Vanadium Oxide (LSVO) battery (126) coupled to the storage capacitors, the LP or LSVO battery providing a charging current to charge the storage capacitors to preselected energy level (full energy); and a recharging circuit (110, 124) coupled to the LP or LSVO battery and configured to deliver recharging current to the LP or LSVO battery (Figs. 3, 8; Col. 7, line 53-Col. 9, line 33).

With respect to claims 14-15, Kroll shows a method of recharging the LP or LSVO battery comprising the step of recharging the LP or LSVO battery to a preselected voltage level (full voltage) (Figs. 3, 8; Col. 11, line 16-Col. 12, line 5).

Regarding claims 3 and 16, Kroll shows the LP or LSVO battery (126) is recharged upon the detection of a predetermined number (1) of deliveries of stimulation energy (Col. 11, line 16-Col. 12, line 5).

With respect to claim 10, Kroll shows a supply battery (124), wherein the recharging circuit (110, 124; 224, 124) is coupled between the supply battery (124) and the LP or LSVO battery (126) (Figs. 3,8).

Regarding claims 11-13, and 25-27, Kroll et al. shows the LP or LSVO battery (126) has a stored energy density and the supply battery (124) has a stored energy density greater than that of the LP or LSVO battery (124); the step of controlling recharging of the SVO battery by the supply battery; the supply battery (124) comprises a relatively high energy density battery and comprises Lithium Carbon Monofluoride (CFx) (Figs. 3, 8; Col. 7, line 53-Col. 9, line 33).

With respect to claims 22-23, Kroll further shows recharging the SVO battery utilizing a recharging current no greater than a preselected value (75mA) to prevent degradation of performance characteristics of the battery, and terminating recharging of the SVO battery (Col. 13, line 8-Col. 14, line 24).

Regarding claim 28, Kroll shows an implantable cardiac rhythm management device comprising a pulse generator (116) adaptively configured to generate electric shocks and comprising at least one output capacitor (150, 152), charging circuitry capable of charging the at least one capacitor to produce high voltage shocks a first battery (126) switchably coupled to the charging circuitry, having the characteristic of a high current flow rate to fast charge the at least one capacitor, a second battery (124), switchably connected in parallel to the first battery, having characteristics that enable the second

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battery to recharge the first battery; a detector (234), coupled to the charging circuitry, that detects when the recharging current is above a predetermined threshold indicative of abnormal recharging of the first battery; and a controller (230) programmed to switchably enable the charging circuitry to produce the high voltage shocks, and to disable the second battery whenever an abnormal recharging current is detected. (Col. 13, line 8-Col. 14, line 24).

With respect to claim 30, Kroll shows the first battery (126) has a battery end of life and the controller is programmed to enable the second battery (124) to recharge the first battery prior to reaching the end of life thereof (Col. 11, line 16-Col. 12, line 5).

Regarding claim 31, Kroll shows the first battery (126) charges the at least one capacitor in a capacitor charge cycle and wherein the controller is programmed to recharge the first battery (126) upon the occurrence of a predetermined number (1) of capacitor charge cycles (Col. 11, line 16-Col. 12, line 5).

With respect to claim 33-35, Kroll shows the first battery comprises a Lithium Pentoxide cell or Lithium Silver Vanadium Oxide (SVO) cell and the second battery comprises a Lithium Carbon Monofluoride (CFx) cell (Col. 7, line 53-Col. 8, line 61).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 5, and 19, are rejected under 35 U.S.C. 103(a) as being obvious over Kroll (5,674,248) in view of Kroll (5,741,307).

With respect to claims 5, and 19, Kroll '248 is as explained before. Although Kroll '248 fails to teach a charging time interval detector, detecting the high voltage capacitor charge time and recharging the SVO battery when the charge time exceeds a preselected value, attention is directed to Kroll '307 which teaches measurement of the charge time in order to indicate inadequate battery strength (Fig. 2; Col. 3, lines 41-49). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Kroll '248 to include a charge time interval detector, to detect the high voltage capacitor charge time and recharge the SVO battery when the charge time exceeds a preselected value, since Kroll '307 teaches measuring of the charge time in order to indicate inadequate battery strength.

16. Claims 5, 19, 29 and 32 are rejected under 35 U.S.C. 103(a) as being obvious over Kroll (6,546,807) in view of Kroll (5,741,307).

With respect to claims 5, and 19, Kroll '807 is as explained before. Although Kroll '807 fails to teach a charging time interval detector, detecting the high voltage capacitor charge time and recharging the SVO battery when the charge time exceeds a preselected value, attention is directed to Kroll '307 which teaches measurement of the

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charge time in order to indicate inadequate battery strength (Fig. 2; Col. 3, lines 41-49).

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Kroll '807 to include a charge time interval detector, to detect the high voltage capacitor charge time and recharge the SVO battery when the charge time exceeds a preselected value, since Kroll '307 teaches measuring of the charge time in order to indicate inadequate battery strength.

Regarding claim 29, Kroll '807 is as explained before. Although Kroll '807 fails to teach the controller is programmed to enable the second battery to recharge the first battery when the voltage across the first battery falls below a predetermined minimum value, attention is directed to Kroll '307 which teaches measurement of the voltage across a battery to determine when the voltage falls below a predetermined minimum value in order to indicate inadequate battery strength (Fig. 2; Col. 3, lines 14-40). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the controller of Kroll '807 to be programmed to enable the second battery to recharge the first battery when the voltage across the first battery falls below a predetermined minimum value since Kroll '307 teaches measuring of the voltage across a battery to determine when the voltage falls below a predetermined minimum value in order to indicate inadequate battery strength.

With respect to claim 32, Kroll '807 is as explained before. Although Kroll '807 fails to teach the controller is programmed to recharge the first battery when the charge cycle time exceeds a preselected value, attention is directed to Kroll '307 which teaches measurement of the charge time in order to indicate inadequate battery strength (Fig. 2; Col. 3, lines 41-49). Therefore, it would have been obvious to one with ordinary skill in

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the art at the time the invention was made to modify the controller of Kroll '807 to be programmed to recharge the first battery when the charge cycle time exceeds a preselected value, since Kroll '307 teaches measuring of the charge time in order to indicate inadequate battery strength.

17. Claim 21 is rejected under 35 U.S.C. 103(a) as being obvious over Kroll et al. (5,674,248). Kroll discloses the claimed invention except for the step of recharging the SVO battery a preselected number of times. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to recharge the SVO battery a preselected number of times, since applicant has not disclosed that recharging the SVO battery a preselected number of times provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any recharging of the SVO battery such as recharging the SVO battery after each stimulation shock as taught by Kroll for maintaining the SVO battery at the desired energy level.

18. Claims 21 and 36 are rejected under 35 U.S.C. 103(a) as being obvious over Kroll (6,546,807).

Regarding claim 21, Kroll discloses the claimed invention except for the step of recharging the SVO battery a preselected number of times. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to recharge the SVO battery a preselected number of times, since applicant has not disclosed that recharging the SVO battery a preselected number of times provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any recharging of the SVO battery such as recharging the SVO battery

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after each stimulation shock as taught by Kroll for maintaining the SVO battery at the desired energy level.

With respect to claim 36, Kroll discloses the claimed invention except for the controller being programmed to periodically recharge the first battery independent of the number of occurrences of the delivery of high voltage shocks. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to periodically recharge the first battery independent of the number of occurrences of the delivery of high voltage shocks, since applicant has not disclosed that this periodic recharging of the first battery independent of the number of occurrences of the delivery of high voltage shocks provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any controller programmed to recharge the first battery such as the controller programmed to recharge the first battery after each stimulation shock as taught by Kroll for maintaining the first battery at the desired energy level.

The applied Kroll (6,546,807) reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application

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and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion

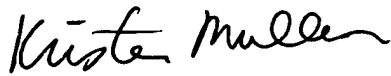
19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Howard et al. (6,650,942) shows an implantable cardiac device with two batteries, one a LiCF_x battery which recharges a LiSVO battery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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